



APR 17 2000

WARNING LETTER

Mr. Benedicto N. Alves, President
Ocean Corporation
Irasan Complex
90 Aquino Avenue
Paranaque City 1700
Metro Manila, Philippines

Dear Mr. Alves:

This is to acknowledge receipt of your letter dated March 13, 2000, responding to our letter dated February 14, 1999, concerning the serious deviations from the U.S. Seafood HACCP regulations (21 CFR Part 123) that we found during our inspection of your firm on May 19, 1999.

- We have reviewed your response and based upon the information you have provided, we do not find your method of controlling histamines in your frozen vacuum packed tuna (treated with "tasteless smoke") to be equivalent to monitoring harvest vessel records or lot-by-lot histamine testing. There is no scientific evidence that we are aware of that supports your claim that histamines, at low levels, can be detected by sensory evaluation. We will accept your method of controlling histamines, if you can supply detailed scientific evidence that sensory monitoring will provide an equivalent control for histamines. This evidence must demonstrate that the sensory evaluations of your employees consistently detect histamine at 30 ppm over an extended period of time in the scromboid species that you process. These evaluations must apply to all employees responsible for making histamine determinations. You must also supply us with:
 - a method by which your firm will verify the accuracy of your employees on a regular basis, and
 - the data you have gathered utilizing this method.
- If, while re-evaluating your method of histamine control, you decide to follow a recommended method of control, please update your HACCP plan accordingly and supply us with a copy of your amended HACCP plan and production records showing your implementation of the changes.

We encourage you to provide us with this information as soon as possible. It is essential that you respond to this office on this matter within six (6) weeks of receipt of this letter. Upon receipt of a timely response, we will work with you to resolve any outstanding issues associated with your HACCP system.

Please send your reply to the:

Food and Drug Administration
Attention: Frank Sikorsky, Consumer Safety Officer
Office of Field Programs, Division of Enforcement and Programs, Import Branch
HFS-606
200 C Street S.W.
Washington, DC 20204.

If you have questions regarding any issue in this letter, please contact Mr. Sikorsky at (202) 205-1922.

Sincerely,

A handwritten signature in black ink, appearing to read "D M Dignan", with a long horizontal flourish extending to the right.

Dennis M Dignan, Ph.D.
Acting Director
Division of Enforcement and Programs
Office of Field Programs
Center For Food Safety
and Applied Nutrition